II. REMARKS

I gratefully acknowledge the telephonic interview granted by Examiner Ruth C. Rodriguez (571-272-7070) on May 31, 2006. I called Examiner Rodriguez to request reconsideration of the finality of the Office Action of March 2, 2006 because the "finality" of the Office Action is premature. Specifically, Examiner Rodriguez had previously indicated that claims 32-35 contained allowable subject matter in the Office Action of September 7, 2005, at 5, lines 4-6. In my Amendment (C), filed December 7, 2005, I amended claims 21 and 31 to incorporate the allowable subject matter of claims 32-35. In the March 2, 2006 Office Action, the Examiner newly rejected claims 21 and 31, which contain subject matter deemed allowable in the September 7, 2005 Office Action, under 35 U.S.C. § 102(b). Because the Examiner has made a new grounds of rejection not necessitated by my amendment, the finality of the March 2, 2006 Office Action is premature. See MPEP § 706.07(a).

Examiner Rodriguez agreed with my contention that the finality of the March 2, 2006 Office Action is premature. Examiner Rodriguez agreed to withdraw finality upon the filing of the present amendment and to enter the present amendment. The withdrawal of finality is proper in accordance with MPEP § 706.07(d).

Claims 21, 31, 36 and 37 have been amended. Specifically, independent claims 21 and 31 have been amended to additionally recite "wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and wherein the first end member removably attaches to the one end of the bar" as supported on page 1, lines 6-10, and on page 4, lines 15-22, of the application as originally filed, and by the paragraph added by Preliminary Amendment (A), filed on October 31, 2003 with the original application, at page 5, lines 9-15, of the Preliminary Amendment (A).

Independent claims 36 and 37 have been additionally amended to recite "and wherein the bar is a straight bar made of metal and the first end member removably attaches to the one end of the bar" as supported on page 1, lines 6-9, and page 2, lines 2-3, and Figures 1 and 11 of the application as

originally filed.

The present amendment adds no new matter to the instant application.

A. The Invention

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37.

Various other embodiments, in accordance with the present invention, are recited in the dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a "mouth and tongue stud" to dispense a substance into a wearer's mouth.

B. The Rejection

Claims 21, 28, 31 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Denney et al. (U.S. Patent 6,047,209, hereafter, the "Denney Patent"). Claims 22-27, 29, 30 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Denny Patent.

Applicant respectfully traverses the rejection and requests reconsideration of the application for the following reasons.

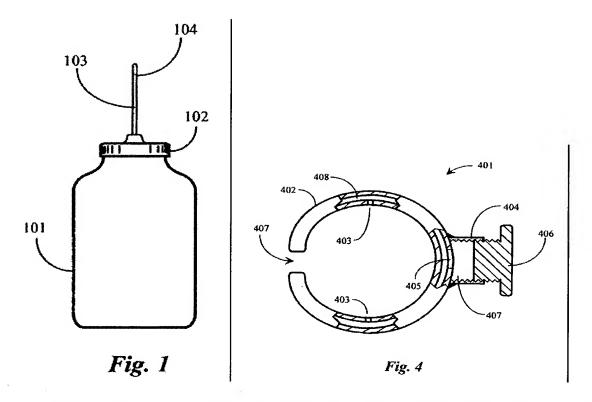
C. Applicant's Arguments

Anticipation under 35 U.S.C. § 102 requires showing the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation to combine the references to produce the claimed invention. In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992); In re Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In the present case, the Section 102 rejection is untenable and must be withdrawn because the Denny Patent fails to teach, or even suggest, a "method for dispensing a substance into a mouth" that includes the step of "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar" and wherein "the first end member removably attaches to the one end of the bar" as recited in independent claims 21, 31, 36 and 37. For the same reason, the Section 103 rejection is untenable and must be withdrawn.

i. The Denny Patent

U.S. Patent 6,047,209, the Denny Patent, teaches a "method and apparatus for maintenance of pierced orifices" for injecting fluid into a pierced body orifice (See Abstract). Specifically, the Denny Patent teaches a "needle" (103) as shown in Figure 3, or a "ring" (401) as shown in Figure 4. Both of these Figures are reproduced below.



Neither apparatus is a "mouth and tongue stud" because neither needle (103) or ring (401) include structure that would allow them to remain in the tongue or other piercing that involves the mouth. Those skilled in the art would realize that the mouth is a very active place so jewelry used in the mouth must have appropriate structure for securing it in place; otherwise, the jewelry will fall out of place and be swallowed or aspirated. The production of saliva, which is a lubricant, makes this problem even more acute. A reasonable person skilled in the art would not place a needle (103), or an unsecurable ring (401), in the mouth of a wearer to maintain a "pierced orifice" because of the hazard created by placing unsecurable objects in the mouth.

In addition, the Denny Patent describes placing the needle (103) in a "pieced orifice" having an interior (302), but the use of hydrogen peroxide, soap and water, and topical antibiotics would reasonably suggest to one skilled in the art that Denney teaches a device for application to "any pierced orifice on the body" (col. 3, lines 28-54, and Figure 3), which would not include piercing involving the mouth. There is nothing in the Denny Patent that teaches, or even suggests, that the method would apply to intraoral piercings.

I have pointed out and clearly shown that the Denny Patent does not teach, or even suggest, devices that are mouth and tongue studs, or that could even be reasonably used in the oral cavity of a wearer. Therefore, the Denney Patent cannot teach, or even suggest, the subject matter of claims 21, 31, 36 and 37 because the reference does not disclose the step of "providing a mouth and tongue stud including a means for dispensing a substance."

However, this is not the only deficiency in the teachings of the Denny Patent. The Denny Patent also does not teach, or suggest, (a) "the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar" and (b) "the first end member removably attaches to the one end of the bar" as recited in independent claims 21, 31, 36 and 36.

As shown in Figure 1 of the Denny Patent, the needle (103) has no "first end member" and no "second end member" as recited in claims 21, 31, 36 and 37. This fact is even more evident from Figure 3 of the Denny Patent, which is reproduced below.

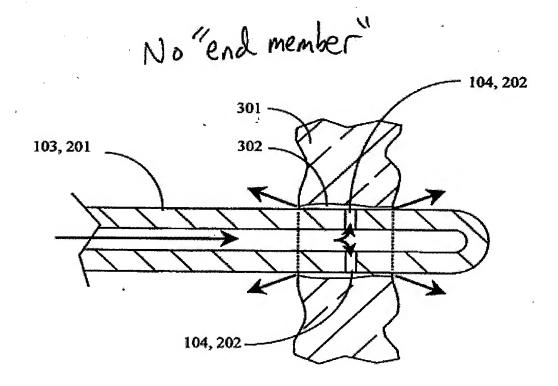


Figure 3 (modified) of the Denny Patent

The Federal Circuit has ruled that the United States Patent and Trademark Office (USPTO) must give a fair reading to what a reference teaches as a whole. In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In the present case, the Denny Patent plainly teaches a device that includes a needle (103) or a ring (401). These are two separate embodiments, yet the Examiner incorrectly refers to these different embodiments as if their parts are interchangeable (Office Action, dated March 2, 2006, at 3, lines 7-15). For instance, the Examiner erroneously contends that base (404) of the embodiment shown in Figure 4 is a "second end member" and that the tip of needle (103) would be the "first end member." Yet these components, (103) and (404), are parts of different devices. The Examiner's contention that needle (103) and base (404) are components of the same device is not supported by any teaching found in the Denny Patent. Furthermore, any contention that the components of the various devices taught by the Denny Patent can be arbitrarily mixed and matched cannot support a rejection under Section 102, which requires the reference teach each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. at 485.

In other words, when the Examiner modifies the devices taught by the Denny Patent in order to meet the limitations of the presently claimed invention, even if only to mix and match parts of different devices, then the Examiner has not established a prima facie case of anticipation. I assert that the Examiner's mixing and matching of parts from different embodiments of the Denny Patent lacks proper motivation and is improper.

Assuming, arguendo, that the components of the needle (103) and the ring (401) could be mixed and matched to make new combinations under Section 103 (which is not a valid assumption), such as the Examiner appears to have done, the Denny Patent still would fail to teach (i) "a first end member attached to one end of the bar" and (ii) "a second end member attached to an other end of the bar" wherein (iii) "the first end member removably attaches to the one end of the bar" as recited in independent claims 21, 31, 36 and 37.

As discussed above, the needle (103) does not have a "first end member" attached to the tip

of the needle as the Examiner contends. There is only the needle (103). For this reason alone, the Examiner's rejection is untenable and must be withdrawn because the Examiner has completely ignored the "first end member" recited in claims 21, 31, 36 and 37. Second, the base (404) of ring (401) taught by the Denny Patent cannot be a "second end member" in accordance with claims 21, 31, 36 and 37 because base (404) is connected to the middle of body (402) and not to "an other end of the bar." Third, the base (404) is not removably attached to the body (402); therefore, the Denny Patent does not teach, or suggest, "the first end member removably attaches to the one end of the bar" as recited by the present independent claims 21, 31, 36 and 37.

The Denny Patent also does not teach, or suggest, that "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by claims 28-30.

As admitted by the Examiner, "once the substance is dispensed upon application it will dissolve over time" (Office Action, March 2, 2006, at 3, lines 2-3). In other words, the Examiner appears to contend that the Denny Patent teaches that once the fluid enters the pierced orifice, it can be absorbed.

The Denny Patent explicitly teaches that its apparatus is "for injecting fluid into a pierced body orifice" (See Abstract, emphasis added). The Denny Patent teaches that when the bottle (101) is squeezed, fluid is sent through the needle openings, such as shown in Figure 3 (col. 3, lines 43-45). With respect to the embodiment of Figure 4, fluid is "manually expressed" into the orifice of the pierced orifice when the knob or plunger (406) is turned (col. 4, lines 52-67).

All of the methods of "dispensing" taught by the Denny Patent involve injecting fluid through a needle (103) or ring body (402). On the other hand, in accordance with embodiments of the present invention recited by claims 28-30, the substance "is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva."

For all of the above reasons, the Examiner has not established a <u>prima facie</u> case of anticipation against the claims of the instant application.

ii. The Section 103 Rejection

A proper rejection under Section 103 further requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. In re Vaeck, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

In this case, the Examiner concedes that the Denny Patent does not teach, or suggest, that "the substance comprises a breath freshener or a flavoring agent or a breath freshener mixed with a flavoring agent" (Office Action, dated March 2, 2006, at 4, lines 6-8). However, the Examiner contends that "it is well known in the art of dispensing medicines into a wearer's mouth to use breath freshener or flavoring agents in combination with the medication to provide an attractive flavor to the medicine being disposed" (Office Action, March 2, 2006, at 4, 12-15).

I am a physician and I am not aware of any medications which include a "breath freshener." Therefore, I respectfully traverse the Examiner's contention that it is well known to add a "breath freshener" to a medication. I remind the Examiner of her obligation under the Administrative Procedure Act to show the evidence on which her findings are based. In re Lee, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002). The Examiner must now provide a prior art reference in support of her contention that breath fresheners are commonly added to medications or withdraw her Section 103 rejection of claims 22, 24, 25, 27 and 36.

The Denny Patent teaches the injection of a "cleaning material," such as a salve, hydrogen peroxide and polysporin, into a pierced orifice (col. 3, lines 34-36, and see Abstract). None of the "cleaning materials" listed by the Denny Patent, whether medicated or not, are the type of material that a person of ordinary skill in the art would consider adding a flavoring agent. Specifically, salve is a topical agent, usually a gel or paste and would not be flavored. A person of ordinary skill in the art would know that flavoring agents are not typically added to hydrogen peroxide solutions. A person of ordinary skill in the art would also know that polysporin preparations, which are used on wounds of the

skin, are not flavored because they are not taken internally by mouth.

In sum, none of the "cleaning materials" or medications listed by the Denny Patent are those that typically would be flavored for oral use or consumption. Therefore, I traverse the Examiner's "official notice" regarding the addition of flavoring agents to "medications" on the grounds that the "official notice" is too broad and the Examiner has not established a proper motivation to justify modifying the "cleaning materials" taught by the Denny Patent to include a flavoring agent. Therefore, the Examiner must now provide a reference that teaches the addition of a flavoring agent to "cleaning materials," such as salve, hydrogen peroxide and polysporin, or withdraw the Section 103 rejection against claims 23, 24, 26, 27 and 36.

For all of the above reasons, the Examiner has not established a <u>prima facie</u> case of obviousness, against the subject matter of claims 21-31, 36 and 37.

III. <u>CONCLUSION</u>

The Examiner has failed to establish either a prima facie case of anticipation or a prima facie case of obviousness against claims 21-31, 36 and 37 of the above-captioned application because the Denny Patent does not teach, or even suggest, the step of (i) "providing a mouth and tongue stud" wherein (ii) "the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar," and (iii) "wherein the first end member removably attaches to the one end of the bar" as recited in independent claims 21, 31, 36 and 37.

For all of the above reasons, claims 21-31, 36 and 37 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed applicant.

Respectfully submitted,

GRIFFIN & SZIPL, PC

W. Scott Ashton, M.D.

Reg. No. 47,395

GRIFFIN & SZIPL, PC Suite PH-1 2300 Ninth Street, South Arlington, VA 22204

Telephone: (703) 979-5700 Facsimile: (703) 979-7429 Customer No.: 24203